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Religion and Medicine:

Why does religion play a role in medical regulation?

A exploration of the role the First Amendment plays in a variety of regulatory schemes to illustrate the impact of the First Amendment upon FDA regulation.

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Abstract

A comparison of the treatment of FDA regulation of religious devices with other intersections between general regulatory schemes and religious freedom. Comparisons included: religious fraud laws, regulation of faith healers under medical practitioner laws, and regulation of Native American religious sites on federal land. Also compared the treatment of the Church of Scientology in three other countries: the United Kingdom, Australia, and Germany with the Church's treatment in the United States. The paper finds that the current approach to federal regulation of medical devices is probably the best way in which to regulate them, with the possible exception of the problems associated with defining religion and religious materials. The paper also finds that the treatment of religions with respect to general regulations is not preferable to the system of medical device regulation existent in the United States.

Genius is oft fleeting and seldom rational. Alexandros Chemedes awoke after a strange dream a few years ago with a strange gift.¹ In the dream, a complicated chemical formula was revealed to Chemedes, along with a voice-over fitting "Field of Dreams" that told him "If you make it..." before the voice cut out. Along with the formula, Chemedes was also shown small spheres being cracked open. With the heart of a true inventor, Chemedes immediately made the formula revealed to him in his dream, and began to experiment with the substance trying to crack open sphere-like objects. This was unsuccessful, but while working with the substance, Chemedes accidentally inhaled some of the substance and his flu symptoms disappeared. In subsequent tests, the substance was shown to crack open the outer shell of a virus in mice, potentially the drug, Miricol, could kill any foreign virus in the body and cure any disease caused by a virus. During the

¹James M. Rose, *Does The FDA Have Jurisdiction Over Miracles?* 72-SEP N.Y. ST. B.J. 64.

extensive testing process, Chemedes was made known of a relative's friend that was dying of a virus causing disease, and wanted to provide the friend with a dosage of the drug to cure the disease. This act would obviously run afoul of the Food and Drug Act, so Chemedes's counsel began searching for an alternative method to allow the distribution of the drug before the drug was approved. One possible argument, was that the drug was divinely inspired because it was revealed to Chemedes in a dream, and that the distribution of the drug was a religious act.² The interesting question from this scenario is how should religion play into food & drug law, which is a clash of science and belief.

This paper hopes to explore this issue by comparing the treatment of religion under the Food and Drug Act with the treatment of religion under comparable comprehensive regulatory schemes. The question is especially pertinent because as health care becomes more involved in the life of the ordinary American by extending the length and quality of her life, both the importance of regulation of health care increases and the place that medical care occupies with respect to the traditional liberties enjoyed by Americans. Cloning, stem cell research, DNA manipulation have enormous medical and religious consequences, and the clash between the regulation of medical practices and religious freedoms, will vault this issue which primarily concerned only non-mainstream religions on the fringe of American society, and will vault the discussion into the public limelight. This paper does not seek to address these concerns, but merely suggest the different possibilities in debating the role of government regulation of medicine and religious freedom.

²The approach that was finally taken was a modified language from the back of parking lot tickets. The language made the sick friend a warehouseman of the product, with a pay of \$10 and explicit instructions to avoid consuming the pills, especially not three times a day for two weeks. The contract had liquidated damages of \$100 dollars and the return of the \$10 bailment fee if the product was not returned. The friend took the pills, was cured and gladly paid the \$100 in damages. When the FDA inquired, they were told that the friend was a poor warehouseman, and could not be trusted. It is unclear whether the FDA agrees the approach is legal, or is rather just a case of prosecutorial discretion because of the limited scope of the violation of the Food and Drug Act. The results of the drug trials are hard to ascertain, as internet searches fail to provide any updates of the condition of Miricol. For more details refer to Rose, *supra* note 1, at 64.

First Amendment Protections of Religion

The traditional approach to appraise the limits of First amendment rights has been to balance the two competing motives of the Free Exercise clause and the Establishment Clause. The Free Exercise clause is limited by a fear that people will use an overly broad religious exception would allow people to become laws unto themselves, whereas the Establishment clause is limited by a fear that courts will become entangled into religious disputes if courts decide too much in religious liberty cases.³ Even the process of defining religion has been difficult for the courts.

The Supreme Court has ruled that certain activities are within the definition of “religion” in the First Amendment, but has not established a prospective rule for what religion is. In *United Sates v. Ballard*, the Court ruled that a new faith was protected by the First Amendment because the religion “embrace[d] the right to maintain theories of life and of death and of the hereafter which are rank heresy to followers of the orthodox faiths.”⁴ That is even though there were not the strictures of “normal” type associated with conventional religions; there was a religion because the faith actively endorsed certain types of behavior, as there was an ethos to the practice of the religion. In *Torcaso v. Watkins*, the Court found a Maryland constitutional provision unconstitutional that required public office holders to swear their faith in a God, a distinction that disfavored religions that do not have a deity in favor of those that do.⁵ The Court also held that religion could include war opposition from a sincere belief of the person to a general goodness that seemed to reside in the same place within a psyche that devotion to God would for a person practicing a

³Jonathan C. Lipson, *On Balance: Religious Liberty And Third-Party Harms*, 84 MINN. L. REV. 589, 593 (2000).

⁴322 U.S. 78, 86-87 (1944).

⁵367 U.S. 488, 495-96 (1961)

conventional monotheistic religion in *United States v. Seeger*.⁶ It is likely but not certain that this definition is applicable to constitutional jurisprudence because the matter came as a result of the interpretation of a statute.

FDA Restrictions on Religious Medical Devices

Generally, the intersection of the FDA's regulatory powers and the question of First Amendment religious concerns have arisen when parties have asserted the First Amendment as a defense when charged with a violation of inadequate directions for use and false labeling sections of the Food, Drug & Cosmetic Act.⁷ The leading case has established that health devices are subject to the requirements for adequate directions for use on labels, notwithstanding the use of such devices with the practice of a religion, and that the regulation of such labels does not infringe the First Amendment if devices are categorized as mislabeled.⁸ In the same case, it was also held that publications of a purely religious nature cannot be considered as labeling, because such a treatment would require the court to determine the truth or falsity of the religious belief in the literature, a practice that is banned by the First Amendment.⁹ The problem in applying this test is how to define religion, and religious materials. This is a hard position for courts to occupy; they are barred from judging religious tenets, but must rule upon whether materials are religious or not. To qualify for the benefits of the religious protections outlined above, one must present the publication as one of religious and not of secular concern.¹⁰

This is a part of the bulwark erected by the courts to separate the two zones: purely religious speech, and the

⁶*See* 380 U.S. 163, 164 (1965).

⁷Sheldon R. Shapiro, Annotation, *Regulation Of Health Devices Under Federal Food, Drug, And Cosmetic Act As Affected By Religious Guaranties Of The First Amendment*, 13 A.L.R. FED. 747 §2(a) (1972).

⁸*See id.*

⁹*See id.*

¹⁰*See id.*

realm which the FDA could regulate. The results from applying these general rules are that if a device with an invalid label that has false scientific claims the FDA can require the product to carry a label warning the device has not been proven to alleviate any disease and that the accompanying literature had false medical or scientific claims even if sold to be used in religious practice.¹¹ This rule isolates any involvement of the government in religious activities by treating them as any other religiously-neutral item sold in commerce. The traditional view is that when the government has created constitutional rules and statutes, violation of the rules or statutes there is no defense for behavior cause by religious belief.¹² The Free Exercise clause does not protect wrongs in the name of religion, or a refusal to obey a general law not aimed at the promotion or restriction of religious beliefs.¹³ This is the rule used by courts in deciding conflict between the FDA and religious groups.

The basic approach in balancing religious freedom with medical regulation has been to construe the limits of the Food, Drug, & Cosmetic Act very broadly in order to protect public health. The limits that the courts have put into place are basically right at the minimum limits of the First Amendment protections for religion, without the protective envelope that is used to buffer core constitutional rights from infringement in other contexts. There are several probable reasons for this. First, courts have not traditionally been very receptive to new or unique religions, as can be seen in decisions referring to the religions in derogatory terms, and this lack of appreciation of complaints about injustice led to abbreviated inquiries into constitutional violations. Second, the area of religious protection encompassed by the Constitution is very amorphous, and there is a concern by the Courts of creating an exception within such a broad and deep regulatory scheme like medical regulation. Finally, there is a long history of medical charlatanism with religious overtones that the statute was passed to prevent and then massively revised in 1938 to expand the strictures against false medical claims, and judges do not want to interpret the statute to allow behavior in conflict with its aims.

¹¹See *id.*

¹²See Donald T. Kramer, 16A AM. JUR. 2D CONSTITUTIONAL LAW § 429 (1998)

¹³See *id.*

Despite a certain amount of judicial and administrative hostility, there are still considerable protections of religious liberty offered by the First Amendment. The requirements from the labeling cases show the courts will try to avoid deciding upon religious matters, which provides religious groups with a lot of freedom to practice their religion.

Another question regarding the definition of religion in the First Amendment is how far the protection goes when churches engage in commercial transactions. In *Tony and Susan Alamo Foundation v. Secretary of Labor*, the Court held that a church engaged in commercial transactions if the activities both served the general public and competed with ordinary commercial enterprises.¹⁴ Thus, the Court held the church's service stations, clothing retail, grocery stores, and hog farms were not exempt under the free exercise clause from the minimum wage requirements of the Fair Labor Standards Act, because the grant of an exemption under the Free Exercise clause would unfairly advantage the church over "ordinary commercial enterprises"¹⁵ In *United States v. Lee*, the Court held that one in a marketplace as a matter of choice cannot claim that religious beliefs should block regulatory schemes that affect others that engage in the activity to deny Amish farmers an exemption from the Social Security system.¹⁶ Even though the farmers were denied the exemption, the opposition to the Social security system was a religious exercise because the Court did not want to be in apposition to judge upon the beliefs of the Amish faith.¹⁷ These holdings are important to FDA conflicts with religious organizations because they establishes that religious status will not exempt an activity from a general regulatory scheme if the activity was commercial.

Religious Fraud

¹⁴ See 471 U.S. 290, 299 (1985).

¹⁵ *Id.*

¹⁶ See 455 U.S. 252, 261 (1982).

¹⁷ See *id.* at 257.

One obvious intersection between religious freedom and government regulation is the prosecution of religious fraud. Because of the sensitive nature of government involvement in religious freedom, religious fraud is rarely prosecuted.¹⁸ This may be due to the appearance that the government is prosecuting religious beliefs, and not really fraud. In *Ballard v. United States*, the Court considered the prosecution of three leaders of the “I Am” faith for federal mail fraud.¹⁹ The leaders claimed the power to heal and in particular one of the leaders claimed to have spoken directly with Jesus and that he was a messenger for Saint Germain.²⁰ The basis for the prosecution was for false statements relating to the leaders’ religious doctrines, because there were not factual statements that could be easily proven false by the prosecutors.²¹ The Court did not allow the jury to decide the correctness of the leaders’ beliefs, because that is a “forbidden domain.”²² The Court did not explicitly decide to test the leaders’ sincerity, although the case is often cited for that principle and has been applied to test sincerity in many contexts from defamation to contempt of court.²³ This is the case that developed the doctrine that courts may not decide questions of religious doctrine, that affects the role of the FDA in regulation of religious healing devices.

The Supreme Court has never directly decided the question of whether the sincerity of criminal defendants in a religious fraud case could be considered.²⁴ There is a tension between the prosecution of generally applicable criminal laws to religious prosecutions, and the fear that the government will be used to evaluate religion. This has lead to the distinction drawn by the Court that the actual basis of the religion may

¹⁸See *United States v. Ballard*, 322 U.S. 78 (1944).

¹⁹See *id.* at 79.

²⁰See *id.*

²¹See *id.*

²²See *id.* at 87.

²³See Stephen Senn, *The Prosecution Of Religious Fraud*, 17 FLA. ST. U. L. REV. 325, 334 (Winter 1990).

²⁴See *id.* at 335.

not be deemed correct or incorrect, but only the sincerity of the beliefs may be considered. There are a variety of ways to consider the sincerity of the defendant in the religious beliefs espoused by the defendant, and thus whether the defendant's behavior was fraudulent. The challenge in defining the evidence used for proof of insincerity is balancing the assumptions drawn from the evidence with the protection of new and non-conventional faiths to the same degree as conventional faiths. For example, courts can refer to evidence of the size and age of a religious organization in deciding religious sincerity, but the court also has to admonish jurors that all religions get the same protection regardless of status, so that new religions will not be disadvantaged by a recent founding date or small number of followers.²⁵ Additionally, courts can consider evidence that the defendant lived in a manner inconsistent with the religious beliefs espoused by the defendant, but this is limited to include non-trivial deviations from the religious dogma, so as to prevent prosecution of founders of religious organizations that fail to follow their beliefs strictly in recognition of the frailty of mankind.²⁶

The balancing of religious protections and regulation of behavior takes an opposite approach than the FDA regulation of religious medical devices. This is because the courts are more concerned with trampling religious freedom by allowing rigorous prosecution of religious fraud, than with preventing the crimes. This is because the tools against fraud could be used to destroy new religions very easily, given that natural incredulity of the average person towards new unconventional faiths and the fact that religious belief is often based in faith, something that is hard to prove. Without the overriding concern of public health, courts are willing to trade some religious fraud in order to create an environment more tolerant of new and unconventional faiths. The problem with this balancing is that religious fraud is more prevalent than it would be otherwise, although the level of religious fraud is probably close to the level of medical violations under the FDA regulatory

²⁵See id. at 343-44.

²⁶See id. at 342-43.

scheme. There is the similar problem that comes from the definition of religion in which courts are left in the untenable position to decide what it can admit based on religious definitions, such as the admission of only non-trivial deviations from religious doctrine. This means that courts are left to decide what is trivial to the religious doctrine of a given church, which is very close to deciding the merit of religious doctrine, which is banned by the Supreme Court.

Regulation of Medical Professionals

The regulation of medical professionals also presents a conflict between a general regulatory scheme and the First Amendment when applied to faith healers. The regulation of doctors in general has been the primary method of controlling the activity of faith healers from the beginning of the 20th century.²⁷ States passed very general statutes to cover all forms of healing that required a healer to register before the practice of medicine.²⁸ These statutes soon included some exceptions for religious healers, for example from the licensing requirements of the statutes.²⁹ The determination of the scope of the exception is accomplished by a three-factor test: “the commercial nature of the healing operation; the relationship of the healer to the organized practice of religion; and the spiritual nature of the means of treatment.”³⁰ This test has been construed to make the exception very small, in order to limit the number of unlicensed practitioners.

²⁷See Comment, *Quackery in California*, 11 STAN. L. REV. 265, 271 (1959)

²⁸See Barry Nobel, *Religious Healing In The Courts: The Liberties And Liabilities Of Patients, Parents, And Healers*, 16 U. PUGET SOUND L. REV. 599, 687.

²⁹See *id.*

³⁰*Id.*

The inquiry into the commercial nature of the healing operation is defined by the *People v. Cole* case, that allows the question of whether the person is within the religious healer exception to go to the jury when the person received compensation for the treatment and the healing occurred outside the confines of a church or house of the defendant.³¹ The present approach by courts is to regard any healing that occurs outside the confines of a church or for a fee with suspicion, and healers may find themselves outside the exception for religious healers if the healing practice appears to be a business.³² This rule dramatically restricts the possibility of faith healers operating in a normal commercial manner, which in turn restricts the number and visibility of religious healers. The acceptance of donations rather than fees, and the practice of faith healing inside the home, has not been enough to avoid the imposition of the licensing requirements upon faith healers in recent cases.³³ This is to prevent mere formalities from creating an end-run around the requirements of the licensing statutes.

The connection between the healer and the church whose tenets the faith healer practices are construed by courts to require a coupling with both the healer and the healing practices to a recognized church.³⁴ This requirement is unconstitutional according to some critics because by favoring recognized churches, the requirement violates the First Amendment Establishment clause.³⁵ This argument is based on the premise that courts can not only allow faith healers that practice the official tenets of their faith without examining the tenets of the religion and favoring the healers that follow the tenets of the faith over those that do not, thereby disfavoring the unofficial healers.³⁶ The proposition is supported by the general line of Supreme Court cases forbidding religious discrimination and a series of lower court decisions that extended exemptions from immunizations for recognized religious groups to include unrecognized religious groups.³⁷

³¹113 N.E. 790, 794-95 (N.Y. 1916).

³²*See Nobel, supra* note 28, at 690.

³³*See id.* at 689.

³⁴*See People*, 113 N.E. at 794.

³⁵*See Nobel* at 691.

³⁶*See id.*

³⁷*See id.* at 691-92. The Supreme Court cases supporting the thesis are: *United States v. Seeger*, 380 U.S. 163 (1965); *Frazee v. Illinois Department of Employment Security*, 489 U.S. 829 (1989); *Employment Division, Oregon Department of Human*

The restriction comes from the desire of the courts to prevent religious healers from inventing a church that exists purely to allow them to practice without a license.

Unlicensed medical practitioners are barred from the diagnosis, treatment, or prescription of drugs, and the exceptions to these prohibitions are read narrowly by the courts, even with religious faith healers.³⁸ The majority of courts only apply the faith healer exception to those healers that only engage in prayer or purely spiritual treatment methods.³⁹ Any further treatment methods are likely to be found criminal, as appellate courts have upheld many convictions of faith healers that undertake more physical palliative measures.⁴⁰ The main concern seems to be of quack doctors circumventing the medical licensing requirements. Courts are additionally very stringent about the use of outside devices in the healing ceremonies. The case of *People v. Estep* saw some Christian faith healers prosecuted for the use of various physical instruments during the healing process.⁴¹ The Esteps claimed the devices were not used to diagnose or treat the patients, rather the devices merely analyzed the patient's life energy.⁴² The court did not find the argument that the devices were not used for healing convincing, and upheld the convictions.⁴³ The reason that the use of devices in religious healing is so stringently enforced is the fear that the devices will be used to give the spiritual treatment a more physical basis, that is convince the patients there is more than an ephemeral quality to the treatment they are receiving. If the faith healers were allowed to use the banned devices in their practice, that would probably increase the number of people healed by faith treatments, which in turn increases the numbers of people treated by unlicensed healthcare practitioners unregulated by the state, a result that courts do not want to allow.

The rigid court interpretation of the exceptions for religious healers, and the small size of the resulting

Resources v. Smith, 494 U.S. 872 (1990); The lower court decisions cited are: *Maier v. Besser*, 341 N.Y.S.2d 411 (N.Y. Sup. Ct. 1972); *Kolbeck v. Kramer*, 202 A.2d 889 (N.J. Super. Ct. Law Div. 1964).

³⁸ See Nobel at 693.

³⁹ See *id.*

⁴⁰ See *id.*

⁴¹ See *People v. Estep*, 104 N.E.2d 562-64 (Ill. App. Ct. 1952).

⁴² See *id.*

⁴³ See *id.* at 567.

exception is very similar to the approach under FDA regulations. The concerns for public health are the driving force behind the strict standards. There is also the concern that people will rely upon the state to assure the quality of medical practitioners, and the allowance of unlicensed practitioners gives the unlicensed practitioners the imprimatur of the state that their medical practice is safe, because the public at large will assume that all medical professionals are regulated without knowing that the religious practitioners are not regulated. This is a problem with heavily regulated fields, the public relies upon the regulation to ensure safety, and any exceptions to the regulations are likely to be unknown to the general public. The FDA regulation of drugs suffers from the same problems with unregulated religious devices, so there is the requirement for labeling. The labeling equivalent here is the restriction upon the actual practice of the faith healers beyond spiritual healing through prayer and other non-physical means. There is a dual recognition that this type of healing likely will cause no harm, and to restrict it would dramatically affect the religious practice of many religions, so the balance weighs in favor of the allowing the practice. When compared to the religious fraud area, there is no overriding public health concern, and the area is not regulated by the government, so there is no concern about reliance upon the government for safety. The result is that the religious freedoms are much broader in that context.

Regulation of Native American Religious Sites

Many Native American religions revolve around ceremonies at sacred locations, the practice of these beliefs often come to a loggerhead with the federal government because of the fact that a large number of these sites are on public land. When the federal government established the reservation system, little to no thought

was given to the religious sensibilities of the Native American tribes, and consequently many areas that were sacred to the tribes became situated in areas of public land outside their control.⁴⁴ The result is an intersection between a large regulatory scheme and religious practice: federal management of the public lands (which comprise approximately 25% of the U.S. land total) with Native American practice of religion. The government is much more involved in the practice of these religions than in the practice of “normal” religions in the Judeo-Christian mode, so the law in this area is interesting. In particular, the government has to straddle two concerns, avoiding abridgement of the Native Americans’ free exercise protection from the First Amendment while not going too far and running afoul of the establishment clause. The free exercise concern is the most analogous to the FDA scenario so it is the one that will be examined here.

The courts have had a long history of rejecting free exercise claims by Native American groups seeking to block development of a particular site by the federal government. In *Sequoyah v. Tennessee Valley Authority*, Cherokee plaintiffs contended the Tennessee Valley Authority’s Tellico Dam would abridge their free exercise rights by denying them access to several sacred sites that would be deluged by the water retained behind the dam.⁴⁵ The district court assumed the sites were central to the practice of the Cherokee religion and access would be denied by the water, but denied the injunction because he interpreted the Free Exercise Clause very narrowly.⁴⁶ The judge reached the decision because the Cherokees were not forced to act in a manner inconsistent with their religious beliefs, and everyone was equally denied access to the sites, regardless of religious persuasion, and in the judge’s words, “An essential element to a claim under the Free Exercise Clause is some form of governmental coercion of actions which are contrary to religious belief.”⁴⁷ The Cherokee claims did not even get this much deference when the case went to the Sixth Circuit on appeal,

⁴⁴Witness the establishment of the federal reservation system, which President Andrew Johnson stated was for the purpose of civilizing and converting the tribes to Christianity. See S. REP. NO. 103-411, at 2 (1994).

⁴⁵See 480 F. Supp. 608, 610 (E.D. Tenn. 1979).

⁴⁶See *id.* at 611-12.

⁴⁷*Id.*

the claims were dismissed because the Cherokees did not prove the centrality of the sites to their religion.⁴⁸

The Supreme Court used similar logic to reach a similar holding in *Lyng v. Northwest Indian Cemetery Protective Association*.⁴⁹ The Forest Service unveiled proposals to issue logging permits and construct a road for access to the timber in the Chimney Rock section of the Six Rivers National Forest, and six Native American tribes sued to enjoin the issuance of permits.⁵⁰ The basis of the suit was the significant religious significance to the tribe, in fact the tribe had a Forest Service Report that stated the road would cause “serious and irreparable” harm to sacred areas both “integral and necessary” to the beliefs of the Native American plaintiffs.⁵¹ The district court found this evidence compelling enough to find the Native Americans could not practice their religion free and unfettered due to the construction of the road, hence, the road construction violated their Free Exercise rights and was enjoined.⁵² The Tenth Circuit decision upheld the lower court decision along the same grounds, absent a finding that the road construction somehow forced the Native Americans to practice their religion in a certain way, the fact they were denied the ability to practice their religion in a full and complete manner was enough.⁵³

The Supreme Court heard the case and overruled the lower court decisions.⁵⁴ Justice O’Connor, delivering the majority opinion, focused upon the fact that Native Americans would be neither “coerced... into violating their religious beliefs” nor penalized in their religious activity by the government action “denying any person

⁴⁸See *Sequoyah v. Tennessee Valley Auth.*, 620 F.2d 1159, 1163-65 (6th Cir. 1980).

⁴⁹See 485 U.S. 439 (1988).

⁵⁰See *Northwest Indian Cemetery Protective Ass’n v. Peterson*, 565 F. Supp. 586 (N.D. Cal. 1983), aff’d 795 F.2d 688 (9th Cir. 1986).

⁵¹*Lyng*, 485 U.S. at 442.

⁵²See *Northwest Indian*, 565 F. Supp. at 591.

⁵³See *Northwest Indian Cemetery Protective Ass’n v. Peterson*, 795 F.2d 688 (9th Cir. 1986).

⁵⁴See *Lyng*, 485 U.S.

an equal share of the rights, benefits, and privileges enjoyed by other citizens.”⁵⁵ The decision denied an effects test, instead focusing upon narrowly drawn lines, according to the Court to avoid problems because “government simply cannot operate if it were required to satisfy every citizen’s religious needs and desires.”⁵⁶ The dissent, authored by Justice Brennan, said there really is no distinction between the government action forcing or prohibiting religious activity and actions that destroy the opportunity for religious activity, that the constitutional inquiry looks to the effects of, not the form of government restraint.⁵⁷

The puzzling thing about this area of religious activity regulation is that the freedoms are construed fairly narrowly like the FDA area and medical licensing areas, but it lacks the compelling public health concern that set the two areas apart from the religious fraud area. The ability of the government to regulate federal land is definitely an important government interest, but it does not seem any more important than preventing religious fraud, so the level of protection allowed should be similar. I think that courts are once troubled by the definition of religion. The court is worried about created an exception to land regulation based in religion because of the amorphous nature of that definition; the concern is that if the exception is created Native American groups could argue against most any governmental alteration of federal land, with the only deciding factors being religion, which the court wants to avoid. In *Lynx*, the court made explicit its unwillingness to create a broader protection by strictly confining the decision to narrowly drawn lines. However, the government interest in using federal land in the manner that it deems most effective may be a more important government concern than the prevention of a few religious frauds, so the protection can be lessened from the religious fraud area.

The true difference between the other situations and the regulation of Native American Indian sites is the

⁵⁵*Id.* at 449.

⁵⁶*Id.* at 452.

⁵⁷*See id.* at 467-69.

concern of the establishment clause. Just as the government cannot regulate pastors in an attempt to restrict religion fraud, the government cannot make a compulsory land choice in favor of the Indians practicing their religion, that might cause an establishment clause violation. When the establishment clause problem is combined with the potential that many government uses of public land would be blocked by creating a religious exception to federal land management, the protection of the Native American Indian sites seems to be a legal Pandora's box that the Court does not want to open.

Comparison of Church of Scientology Treatment

The Church of Scientology is one of the fastest growing worldwide of the new religions that have sprouted in the last fifty years. The Church has been treated vastly differently depending upon the country in which it was located, and how the Church was treated with regard to large regulatory schemes seems to be an interesting comparative problem to explore for the purposes of this paper.

United States

Probably the most important case involving the Church of Scientology, and the case that inspired this paper, was an action commenced by the FDA by the seizure of many of the Church's E-meters and publications.⁵⁸

⁵⁸See *United States v. Article or Device*, 333 F. Supp. 357 (D.D.C. 1971).

The FDA contended that the E-meters, as used by the Scientologists, constituted a violation of the Food, Drug and Cosmetic Act.⁵⁹ The used violated the prohibition against devices with false and misleading labeling, with the labeling being the publications that claimed the use of the device in “auditing” could cure various physical and mental ailments.⁶⁰

On appeal, the decision of whether the labeling was false or misleading depended upon the whether the group constituted a religion, which there was immense contention over at the trial level.⁶¹ This resulted because if the court ruled the statements “false or misleading,” and Scientology were a religion, the court would have found “that their religious doctrines were false.”⁶² The court set forth a doctrinal wall, separating all materials that set “forth religious doctrine” would be excluded for the purposes of showing misleading labeling because of the Supreme Court precedent in *United States v. Ballard*,⁶³ that would have made the alternative fraught with “the gravest constitutional difficulties.”⁶⁴ The line, however, did not exclude all literature published by the church from the mislabeling consideration. The issue was retried and the district court came to the conclusion that the use of E-meters was permitted by the statute, but only “for use in bona fide religious counseling.”⁶⁵ The ruling prohibited any secular use of the E-meters, and required that the meters contain a warning to show that there is not “any medical or scientific basis for believing or asserting that the device is useful in the diagnosis, treatment, or prevention of any disease.”⁶⁶ The court additionally required limits on the literature distributed along with the E-meters.

An important fact to note is that the court separates the religious literature so that a disbelief of the religion does not harm the case of the defendant. This is despite the court’s skeptical view of the Church. The

⁵⁹See *Founding Church of Scientology v. United States*, 409 F.2d 1146, 1148 (D.C. Cir. 1969).

⁶⁰See *id.*

⁶¹See *id.* at 1156.

⁶²*Id.*

⁶³See 322 U.S. 78 (1944).

⁶⁴*Founding Church of Scientology*, 409 F.2d at 1157.

⁶⁵See *United States v. Article or Device*, 333 F. Supp. 357, 364 (D.D.C. 1971).

⁶⁶*Id.*

ruling allows the Church to carry out all of its “bona fide religious counseling,” with only a limitation on the secular use of the devices, and the fact that all of the literature had to contain disclaimers. This means that the Church is largely allowed to practice Scientology without fetter. The analysis does set forth a difficult test that calls for the court to determine which materials set forth religious doctrine, which is difficult for all of the reasons discussed above. The fact that there are the disclaimers at all, is a reflection that the medical device area is a strictly regulated area by the FDA, and so there is a need to retain a keep nonscientific claims off of the market as discussed above in the general FDA section and the medical licensing section.

United Kingdom

The United Kingdom, without a written constitution, does not have the equivalent of a written protection for the free exercise of religion like the United States.⁶⁷ The protection has been historically provided by the common and acts of Parliament.⁶⁸ The fact that the Church of England remains the established church of the country means there is no equivalent to the establishment cause from the United States Constitution. The treatment of minority faiths has been one of “tolerance,” but the limits of this toleration vary greatly by the individual faith.⁶⁹ When the Church of Scientology became established in the United Kingdom in the 1960s, there was a large conflict between the Church and the government. The first attack came from the Ministry of Health, with an announcement that the Church was “socially harmful,” that accompanied a ban on foreign nationals seeking to proselytize for the Church.⁷⁰ This is allowed under British law because

⁶⁷ See S.H. Bailey et al., *CIVIL LIBERTIES: CASES AND MATERIALS* (3d ed. 1991).

⁶⁸ See *id.* at 1-12.

⁶⁹ See A. Bradney, *RELIGIONS, RIGHTS AND LAWS* 3, 9 (1993).

⁷⁰ Bailey, et al., *supra* note 200, at 560 (citing 769 H.C. Deb., 25 July 1968, written answers, col. 189).

there is no specific control on the British government that is external to the laws passed by Parliament, so the government in power has the ability to push the level of protections without much interference besides a very limited judicial review when compared to the United States. This may change with the admission of United Kingdom to almost all aspects of the European Union, along with human rights treaties that guarantee certain religious freedoms.

There were inevitably conflicts between the government and the Church when the Church came under the umbrella of a extensive governmental regulation. In one case, the Church of Scientology attempted to name a chapel at their headquarters a “place of meeting for religious worship” to qualify for tax benefits.⁷¹ Thus, the British courts had to determine whether the chapel was indeed used for religious purposes. The court ruled that “place of meeting for religious worship” required a group to gather to express reverence to God, any God satisfies the requirement, so long as there is “reverence to a deity.”⁷² The court then explains there may be exceptions, such as Buddhist temples, but that Scientology was not one of the exceptions.⁷³ The Court explained that Scientology was more of a philosophy about existence rather than a reverence to a deity.⁷⁴ The court did not explain exactly what qualifications are necessary to qualify under the Buddhism exception rather than the obvious fact that Buddhism is a centuries-old religion with millions of adherents, while Scientology was a decade-old creation of a science fiction writer with rather limited talent with followers numbering in the thousands.⁷⁵

Paul Horwitz pointed out that while the United Kingdom claims to protect religion through neutrality, these protections quickly dissolve when religions are faced hostile eyes from political and judicial officials.⁷⁶ The

⁷¹*R. v. Registrar General, Ex p. Segerdal*, 2 Q.B. 697, 701-704 (Eng. C.A. 1970).

⁷²*Id.* at 707.

⁷³*See id.*

⁷⁴*See id.*

⁷⁵*See id.*

⁷⁶*See* Paul Horwitz, *Scientology in Court*, 47 DEPAUL L. REV. 85, 114 (Fall 1997).

British courts were unwilling to classify Scientology as a religion, first because there is a view, prevalent in many locations besides the United Kingdom, that Scientology is at best a money-making pyramid scheme and at worst a cult of some type. The second is that British courts have historically not had to do the rigorous definition of religion that United States courts have had to as a result of the First Amendment, and they do not seem to want to engage in such navel examination at this time. Instead of trying to separate out the religious from the secular components of the religious practice of the Scientologists, the British courts have just denied the Scientologists religious status. That being said, the Scientologists are now able to practice in the United Kingdom with little official interference from the government, the church is just unavailable to take advantage of many exceptions to general rules allowed for religious organizations. This approach is very similar to the view taken by the IRS in the United States, until recently when the IRS decided to allow the Church of Scientology to gain tax exempt status under the federal income tax laws.

Australia

Australia provides an interesting contrast to the United Kingdom and United States, because while Australia has a written protection of religious freedom in its constitution, Section 116, the protections afforded by this clause are more limited than those of the First Amendment.⁷⁷ The protection under Section 116 only prohibits laws intended to interfere with an established religious freedom, a stricter test than under the First Amendment.⁷⁸ Within this framework, Australia has also been very hostile to the Church of

⁷⁷ See Beth Gaze & Melinda Jones, LAW, LIBERTY AND AUSTRALIAN DEMOCRACY 245 (1990).

⁷⁸ See Stephen McLeish, *Making Sense of Religion and the Constitution: A Fresh Start for Section 116*, 18 MONASH U. L. REV. 207, 209 (1992).

Scientology. There is a history of laws banning Scientology, and monitoring of Church members by the Australian Intelligence Organization.⁷⁹ However, when the Church tried to claim a tax exemption as a religious institution, the Church found a more receptive audience in the Australian court system.⁸⁰ The Australian court adopted a multi-factor test for the definition of religious institution, in rejection of the English definition.⁸¹ The court's definition was a relatively broad test that first looked to the belief in a "Supernatural Being, Thing, or Principle," then to whether there was "acceptance of canons of conduct in order to give effect to that belief."⁸² This test may be less strict than the British test because of the necessity to include Aboriginal religions, a problem that the United Kingdom courts would need not consider.⁸³

The Australian example is an interesting contrast between the United Kingdom and the United States. The Australian government position was more hostile to Scientology than that of the United States and the United Kingdom, but the Australian court system recognized the Church as a religion back in 1983 for tax purposes, before either other country. This can probably be linked to the fact that Australia is a multi-religious society with the majority Christian population and the minority Aborigine population. The Aborigine religion defies the traditional Western view of religion, with an emphasis on the land and its relationship to the people that inhabit it. The British definition would not protect the Aboriginal religion, so the Australian court had to adopt a broader test that not only looked to a belief in God, but basically a belief in a greater principle than man. It is arguable if Scientology actually meets this test, because the focus of Scientology is to purge the infallible human mind of problems, man is viewed as the pinnacle of creation. The Australian test is probably very similar to that of the United States, in the United States scenarios discussed above, the courts would probably reach the same decision on religious status as their United States counterparts. The interesting question is whether the Australian court allowed the tax exemption with no secular restraints because there

⁷⁹See *Church of the New Faith v. Commissioner for Payroll Tax (Vic.)*, 154 C.L.R. 120 (1983).

⁸⁰See *id.*

⁸¹See *id.* at 137, 140-41.

⁸²*Id.* at 136.

⁸³See *id.* at 151.

was no real compelling need to do so. In other words, if the Australian courts were facing a case similar to the labeling case, would the court pragmatically impose secular restraints such as the United States courts, or would the Australian courts give the Scientologists leave to practice their religion without hindrance. I would expect the Australian courts to follow the lead of the United States brethren because I suspect that the reason the religious test was so wide in this case was to allow for incorporation of Aboriginal religions, and in the medical device area would still allow Scientology to have religious status, but with significant restraints upon the use of the devices.

Germany

Germany is another constitutional country that offers protection for religion within its constitution. The clause protects “[f]reedom of faith, of conscience, and freedom of creed, religious or ideological” as inviolable.⁸⁴ The protection is broader than the other protections in other countries in this paper, because it protect religions, creeds and philosophies, so the German courts do not have to enter into decision about whether a belief system is a religion to see if something qualifies for protection.⁸⁵ There is also a clause that states “[t]he undisturbed practice of religion is guaranteed.”⁸⁶ This right is not seen as absolute, but are proportional to other rights that might be at stake in a given context.⁸⁷ These broad rights are limited in practice because freedoms guaranteed by the constitution may not be used “combat the basic order,”

⁸⁴David P. Currie, THE CONSTITUTION OF THE FEDERAL REPUBLIC OF GERMANY 344 (1994)

⁸⁵See Horwitz, at 119.

⁸⁶See Currie, at 344.

⁸⁷See Dieter Grimm, HUMAN RIGHTS AND JUDICIAL REVIEW IN GERMANY, IN HUMAN RIGHTS AND JUDICIAL REVIEW: A COMPARATIVE PERSPECTIVE 267, 275 (David M. Beatty ed., 1994).

so political parties and groups that wish to challenge the democratic order are illegal.⁸⁸ The German constitutional scheme, as opposed to the United States scheme of protecting rights by restraining government intrusion into private rights, is seen to create freedom by active government involvement in the protection of rights.⁸⁹ In terms of church-state relations, Germany can be seen as “pro-religion,” and allows religious organizations fairly wide latitude under the law.⁹⁰ This results in the definition of “religious community” to be drawn fairly narrowly in order to prevent the abuse of the definition to include “dubious commercial enterprises calling themselves ‘religions’ in order to escape the narrow limits of commercial, social, and competition law.”⁹¹

This view has colored the treatment the Church of Scientology as several moves by the German government that treat the Church as a anti-democratic menace, from wire-taps on Scientology offices to a ban on Scientologists within the state government of Bavaria.⁹² One case involving the Church in Germany was a claim by a former staff member that received a minimum wage to test Church applicants, and thus he was protected by the national labor laws because of the resulting labor contract.⁹³ The Church tried to use religion as a shield to these regulations, because the member was a member due to the religious relationship, there was no employer-employee relationship.⁹⁴ The court stated a test for a religious community involving both the acceptance and the expression of a common religion or creed show by communal action and belief; however, the court added that a religious community could lose the protection of such a status if the community acted to further commercial rather than religious aims. The court found that the Church did fall

⁸⁸See Currie, at 352.

⁸⁹W. Cole Durham, GENERAL ASSESSMENT OF THE BASIC LAW—AN AMERICAN VIEW, IN *GERMANY AND ITS BASIC LAW: PAST, PRESENT AND FUTURE—A GERMAN-AMERICAN SYMPOSIUM* 37, 45 (Paul Kirchhof & Donald P. Kommers eds., 1993).

⁹⁰Martin Heckel, *Religious Human Rights in Germany*, 10 EMORY INT’L. L. REV. 107, 108 (1996).

⁹¹Martin Heckel, THE IMPACT OF RELIGIOUS RULES ON PUBLIC LIFE IN GERMANY, IN *RELIGIOUS HUMAN RIGHTS IN GLOBAL PERSPECTIVE: LEGAL PERSPECTIVES* 191, 203 (Johan D. van der Vyver & John Witte, Jr. eds., 1996)

⁹²Alan Cowell, *Germany Will Place Scientology Under Nationwide Surveillance*, N.Y. TIMES, June 7, 1997, at A1; *Bavaria Asks Disclosure of Scientology Ties*, N.Y. TIMES, Oct. 30, 1996, at A6

⁹³See Religionsgemeinschaftseigenschaft von Scientology <<http://www.mpikgteltow.mpg.de/people/katinka/fishy/5azb2194.html>>

⁹⁴See id.

out of the protection because of several commercial like actions from high membership fees to fines levied against slow-selling church staff members. Therefore, the court ruled against the Church, and imposed the requirements of the labor regulatory scheme upon the Church.⁹⁵

Germany has the least permissive attitude towards the Church of Scientology, despite having the broadest protection for belief for belief of countries in this paper. This is a result of rights being lost if in a challenge to the democratic order, hence the Nazi party today would not be able to organize to take over the Chancellery as they did in 1934. The result of this that the government can crack down fairly harshly upon groups that it views as threats to democracy. Because the Church of Scientology is seen as an anti-democratic group, the German government can freely deny the Church of Scientology the right to organize in Germany. The restriction on the term “religious organization” is a way to favor the established churches in Germany that are seen a socially stabilizing force, so much that tax monies are use to support churches. This is a completely different model that the United States, and bears little relation to the United Kingdom and Australia where the church and state are not so intertwined. The only real possible application for United States law is the way that German law draws a tighter definition for religious exemption from pervasive regulatory schemes than for religious protection. This scheme if correctly applied could expand religious protection while avoiding the problem of creating huge exceptions to general regulatory schemes.

Conclusion

⁹⁵ *See id.*

After reviewing the various interfaces between large regulatory schemes and religious practices, there is no overwhelming recommendation to make to alter the current treatment of religious conflicts with FDA regulation, but there are several conclusions that can be made. First, the current system seems to balance the interests of religion and public safety well, the comparisons to the similar but slightly changed regimes in a perturbation theory type of analysis showed that slightly different changes to the area could lead to different levels of protection. The only real adjustment to the system, if possible, would be to eliminate the court determination of religion and religious material. It would be ideal if courts did not have to engage in these determinations for the reasons listed above, but it is likely that it is impossible for courts to fully extract themselves from the quagmire that accompanies the definition of religion. Second, the comparison of the FDA regime to the regulation of the United Kingdom, Australia and Germany showed that the protection of religious freedom can easily be abridged even if there are protections for religious liberty by government action and restrictive definitions of religion. The United States is somewhat shielded from this problem by the lack of definition of religion by the Supreme Court that allows a broad view of it, and the strict interpretation of the First Amendment to prevent restrictive governmental action. The schemes enacted in these countries could not be enacted in the United States because the protections of religious freedom is just not to the level of the First Amendment, and it remains to be seen if the more restrictive standards offer more protection than the United States' more hands off approach. Finally, the area of religious land protection needs to be revisited by the Supreme Court because the current regime is far too oppressive to carry out the goals espoused in the *Lyng* decision, although that is a topic for a separate paper.